§ 22.51 Presiding Officer.

The Presiding Officer shall be a Regional Judicial Officer. The Presiding Officer shall rule on all motions until an initial decision has become final or has been appealed.

§ 22.52 Information exchange and discovery.

Respondent's information exchange pursuant to § 22.19(a) shall include information on any economic benefit resulting from any activity or failure to act which is alleged in the administrative complaint to be a violation of applicable law, including its gross revenues, delayed or avoided costs. Discovery under § 22.19(e) shall not be authorized, except for discovery of information concerning respondent's economic benefit from alleged violations and information concerning respondent's ability to pay a penalty.

§ 22.53 Interlocutory orders or rulings.

Interlocutory review as set forth in § 22.29 is prohibited.

Appendix A to Part 22—Addresses of EPA Regional Offices and Headquarters

Environmental Protection Agency, *Region I*—John F. Kennedy Federal Building, One Congress Street, Boston, MA 02203.
Environmental Protection Agency, *Region II*—290 Broadway, New York, NY 10007–1866.
Environmental Protection Agency, *Region III*—841 Chestnut Building, Philadelphia, PA, 19107.
Environmental Protection Agency, *Region IV*—Atlanta Federal Center, 100 Alabama Street, S.W., Atlanta, GA 30365.
Environmental Protection Agency, *Region V*—77 West Jackson Boulevard, Chicago, IL 60604-3590.
Environmental Protection Agency, *Region VI*—First Interstate Bank Tower and Fountain Place, 1445 Ross Avenue, 12th Floor, Suite 1200, Dallas, TX 75202–2733.
Environmental Protection Agency, *Region VII*—726 Minnesota Avenue, Kansas City, KS, 66101.
Environmental Protection Agency, *Region VIII*—999 18th Street, Suite 500, Denver, CO 80202-2466.
Environmental Protection Agency, *Region IX*—75 Hawthorne Street, San Francisco, CA 94105.
Environmental Protection Agency, *Region X*—1200 6th Avenue, Seattle, WA 98101.
Environmental Protection Agency, *Headquarters*, 401 M Street, S.W., Washington, D.C. 20460.

Appendix B to Part 22—Addresses of Regional and Headquarters Lockboxes

Superfund (all Regions)—(Mellon Bank) EPA—Superfund, PO Box 371003, Pittsburgh, PA 15251–7003
Region I—(Mellon Bank) EPA Region I Hearing Clerk, PO Box 360197, Pittsburgh, PA 15251-6197
Region II—(Mellon Bank) EPA Region II Hearing Clerk, PO Box 360188, Pittsburgh, PA 15251–6188
Region III—(Mellon Bank) EPA Region III Hearing Clerk, PO Box 360515, Pittsburgh, PA 15251–6515
Region IV—(The Citizens and Southern National Bank) EPA Region IV Hearing Clerk, PO Box 100142, Atlanta, GA 30384
Region V—(The First National Bank of Chicago) EPA Region V Hearing Clerk, PO Box 70753, Chicago, Il 60673
Region VI—(Mellon Bank) EPA Region VI Hearing Clerk, PO Box 360582, Pittsburgh, PA 15251–6582
Region VII—(Mellon Bank) EPA Region VII Hearing Clerk, PO Box 360748, Pittsburgh, PA 15251–6748
Region VIII—(Mellon Bank) EPA Region VIII Hearing Clerk, PO Box 360859, Pittsburgh, PA 15251–6859
Region IX—(Mellon Bank) EPA Region IX Hearing Clerk, PO Box 360863, Pittsburgh, PA 15251–6863
Region X—(Mellon Bank) EPA Region X Hearing Clerk, PO Box 360903, Pittsburgh, PA 15251–6903
Headquarters—(Mellon Bank) EPA Headquarters Hearing Clerk, PO Box 360277, Pittsburgh, PA 15251–6277.

PART 59—[AMENDED]

1. The authority citation for Part 59 continues to read as follows:

Authority: 42 U.S.C. 7413(d)(3).

2. Part 59 proposed on May 3, 1994 at (59 FR 22776) is amended by removing subpart B.

[FR Doc. 98–4520 Filed 2–24–98; 8:45 am]
BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300619; FRL–5772–7]

RIN 2070–AB78

Prometryn; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA proposes to establish tolerances for residues of prometryn in or on carrots under its own initiative to harmonize tolerances with Canada under the Federal Food, Drug and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1966 (Pub. L. 104–170).

DATES: Comments, identified by the document control number [OPP–300619], must be received on or before March 27, 1998.

ADDRESSES: By mail, submit written comments to: Public Response and Program Resources Branch, Field Operations Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, M St., SW, Washington, DC 20460. In person, bring comments to: Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202.

Comments and data may also be submitted electronically to: opp-docket@epamail.epa.gov. Follow the instructions under Unit V. of this document.

Information submitted as a comment concerning this notice may be claimed confidential by marking any part or all of that information as ''Confidential Business Information'' (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in Rm. 119 at the address given above, from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail: James A. Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 308-5697, e-mail: tompkins.james@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA is proposing under its own initiative that 40 CFR 180.222 be amended by establishing tolerances for residues of the herbicide prometryn, 2,4-bis(isopropylamino)-6-methylthio-s-triazine in or on carrots at 0.1 parts per million (ppm) without a U.S. registration under the Federal Insecticide Fungicide Act (FIFRA), as amended for carrots imported from Canada.

I. Risk Assessment and Statutory Findings

New section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes

exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides based primarily on toxicological studies using laboratory animals. These studies address many adverse health effects, including (but not limited to) reproductive effects, developmental toxicity, toxicity to the nervous system, and carcinogenicity. Second, EPA examines exposure to the pesticide through the diet (e.g., food and drinking water) and through exposures that occur as a result of pesticide use in residential settings.

A. Toxicity

1. *Threshold and non-threshold effects.* For many animal studies, a dose response relationship can be determined, which provides a dose that causes adverse effects (threshold effects) and doses causing no observed effects (the ''no-observed effect level'' or ''NOEL'').

Once a study has been evaluated and the observed effects have been determined to be threshold effects, EPA generally divides the NOEL from the study with the lowest NOEL by an uncertainty factor (usually 100 or more) to determine the Reference Dose (RfD). The RfD is a level at or below which daily aggregate exposure over a lifetime will not pose appreciable risks to human health. An uncertainty factor (sometimes called a ''safety factor'') of 100 is commonly used since it is assumed that people may be up to 10 times more sensitive to pesticides than the test animals, and that one person or subgroup of the population (such as infants and children) could be up to 10 times more sensitive to a pesticide than another. In addition, EPA assesses the potential risks to infants and children based on the weight of the evidence of the toxicology studies and determines whether an additional uncertainty factor is warranted. Thus, an aggregate daily exposure to a pesticide residue at or below the RfD (expressed as 100% or less of the RfD) is generally considered acceptable by EPA. EPA generally uses the RfD to evaluate the chronic risks posed by pesticide exposure. For shorter term risks, EPA calculates a margin of exposure (MOE) by dividing the estimated human exposure into the NOEL from the appropriate animal study. Commonly, EPA finds MOEs lower than 100 to be unacceptable. This 100-fold MOE is based on the same rationale as the 100-fold uncertainty factor.

Lifetime feeding studies in two species of laboratory animals are conducted to screen pesticides for cancer effects. When evidence of increased cancer is noted in these studies, the Agency conducts a weight of the evidence review of all relevant toxicological data including short-term and mutagenicity studies and structure activity relationship. Once a pesticide has been classified as a potential human carcinogen, different types of risk assessments (e.g., linear low dose extrapolations or MOE calculation based on the appropriate NOEL) will be carried out based on the nature of the carcinogenic response and the Agency's knowledge of its mode of action.

2. *Differences in toxic effect due to exposure duration.* The toxicological effects of a pesticide can vary with different exposure durations. EPA considers the entire toxicity data base, and based on the effects seen for different durations and routes of exposure, determines which risk assessments should be done to assure that the public is adequately protected from any pesticide exposure scenario. Both short and long durations of exposure are always considered. Typically, risk assessments include ''acute,'' ''short-term,'' ''intermediate term,'' and ''chronic'' risks. These assessments are defined by the Agency as follows.

Acute risk, by the Agency's definition, results from 1-day consumption of food and water, and reflects toxicity which could be expressed following a single oral exposure to the pesticide residues. High end exposure to food and water residues are typically assumed.

Short-term risk results from exposure to the pesticide for a period of 1-7 days, and therefore overlaps with the acute risk assessment. Historically, this risk assessment was intended to address primarily dermal and inhalation exposure which could result, for example, from residential pesticide applications. However, since enaction of FQPA, this assessment has been expanded to include both dietary and non-dietary sources of exposure, and will typically consider exposure from food, water, and residential uses when reliable data are available. In this assessment, risks from average food and water exposure, and high-end residential exposure, are aggregated. High-end exposures from all 3 sources are not typically added because of the very low probability of this occurring in most cases, and because the other conservative assumptions built into the assessment assure adequate protection of public health. However, for cases in which high-end exposure can reasonably be expected from multiple sources (e.g. frequent and widespread homeowner use in a specific geographical area), multiple high-end risks will be aggregated and presented as part of the comprehensive risk assessment/characterization. Since the toxicological endpoint considered in this assessment reflects exposure over a period of at least 7 days, an additional degree of conservatism is built into the assessment; i.e., the risk assessment nominally covers 1-7 days exposure, and the toxicological endpoint/NOEL is selected to be adequate for at least 7 days of exposure. (Toxicity results at lower levels when the dosing duration is increased.)

Intermediate-term risk results from exposure for 7 days to several months. This assessment is handled in a manner similar to the short-term risk assessment.

Chronic risk assessment describes risk which could result from several months to a lifetime of exposure. For this assessment, risks are aggregated considering average exposure from all sources for representative population subgroups including infants and children.

B. Aggregate Exposure

In examining aggregate exposure, FFDCA section 408 requires that EPA take into account available and reliable information concerning exposure from the pesticide residue in the food in question, residues in other foods for which there are tolerances, residues in groundwater or surface water that is consumed as drinking water, and other non-occupational exposures through pesticide use in gardens, lawns, or buildings (residential and other indoor uses). Dietary exposure to residues of a pesticide in a food commodity are estimated by multiplying the average daily consumption of the food forms of that commodity by the tolerance level or the anticipated pesticide residue level. The Theoretical Maximum Residue Contribution (TMRC) is an estimate of the level of residues consumed daily if each food item contained pesticide residues equal to the tolerance. In evaluating food exposures, EPA takes into account varying consumption patterns of major identifiable subgroups of consumers, including infants and

children. The TMRC is a ''worst case'' estimate since it is based on the assumptions that food contains pesticide residues at the tolerance level and that 100% of the crop is treated by pesticides that have established tolerances. If the TMRC exceeds the RfD or poses a lifetime cancer risk that is greater than approximately one in a million, EPA attempts to derive a more accurate exposure estimate for the pesticide by evaluating additional types of information (anticipated residue data and/or percent of crop treated data) which show, generally, that pesticide residues in most foods when they are eaten are well below established tolerances.

Percent of crop treated estimates are derived from federal and private market survey data. Typically, a range of estimates are supplied and the upper end of this range is assumed for the exposure assessment. By using this upper end estimate of percent of crop treated, the Agency is reasonably certain that exposure is not understated for any significant subpopulation group. Further, regional consumption information is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups, to pesticide residues. For this pesticide, the most highly exposed population subgroup (non-nursing infants >1 year old) was not regionally based.

II. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action, EPA has sufficient data to assess the hazards of prometryn, and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a tolerance for residues of prometryn and its metabolite on carrots at 0.1 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by prometryn are discussed below.

1. A rat acute oral study with a LD_{50} of 1,802 milligrams/kilogram (mg/kg) for males and a LD_{50} of 2,076 mg/kg for females

2. A 28-day mice pilot feeding study with a No Observed Effect Level (NOEL) of 450 milligrams/kilogram/day (mg/kg/day) and a Lowest Observed Effect Level (LOEL) of 1,500 mg/kg/day based on decreased body weights.

3. A 21-day dermal toxicity study with a NOEL and LOEL greater than of 1,000 mg/kg/day the highest dose tested (HDT).

4. A 102-week chronic feeding/carcinogenicity study in mice with a Systemic NOEL of 100 mg/kg/day for females and a Systemic LOEL of 300 mg/kg/day for females based on decreased body weight gain. No effects were observed in males. Although significant toxicity was observed only in females, the Health Effects Division Reference Dose (RfD) committee considered the study adequate since (1) levels were close to one-half the limit dose in mice; (2) no effects were noted in the study to warrant repeating the study at high dose levels; and (3) all tumors noted with other members of the s-triazine class were mainly in rats and not mice.

5. A 2-year rat chronic feeding/carcinogenicity study with a Systemic NOEL of 29.45 mg/kg/day for males and 37.25 mg/kg/day for females and a Systemic LOEL of 60.88 mg/kg/day for males and 80.62 mg/kg/day for females based on decreased body weight and body weight gain and an increase in the incidence of renal lesions (mineralized concretions) in males. prometryn was not oncogenic under the conditions of the study.

6. A 106-week dog feeding study with a NOEL of 3.75 mg/kg/day and a LOEL of 37.5 mg/kg/day based on degenerative hepatic changes, renal tubule degeneration, and bone marrow atrophy. Prometryn was not oncogenic under the conditions of the study.

7. A developmental toxicity study in rats with a Maternal and Developmental NOEL of 50 mg/kg and a Maternal LOEL of 250 mg/kg based on salivation and decreases in body weight and food consumption. The Developmental LOEL is 250 mg/kg/day based on significantly decreased and incomplete ossification in the sternebrae and metacarpals.

8. A developmental toxicity study in rabbits with a Maternal and Developmental NOEL of 12 mg/kg/day and a Maternal LOEL of 72 mg/kg based on based on decreased food consumption, and the Developmental LOEL of 72 mg/kg/day, based on increased fetal resorptions.

9. A two-generation reproduction study in rats with a Parental Systemic NOEL of 0.6 mg/kg/day in males and 0.7 mg/kg/day in females and a Parental Systemic LOEL of 47.8 mg/kg/day in males and 53.6 mg/kg/day in females based on decreased food consumption, body weight and body weight gain. The Reproductive Systemic NOEL is 0.65 mg/kg/day and the Reproductive Systemic LOEL is approximately 50 mg/kg/day, based on decreased pup weight.

10. An Ames *salmonella* test, prometryn was negative for gene mutation up to cytotoxic solubility limits (1,000-2,000 µg/plate). A chromosomal aberration *in vivo* Chinese hamster bone marrow test, prometryn was negative for nuclear anomalies (micronuclei) when animals were dosed orally up to 5,000 mg/kg. Prometryn was negative for bacterial DNA repair and gene mutation up to precipitating levels (1,000 µg/plate). An unscheduled DNA synthesis test prometryn was negative (measured as UDS) in rat hepatocytes cultured *in vitro* up to cytotoxic levels (156.25 µg/mL).

11. Rat metabolism studies showed that radio labeled prometryn is distributed in blood greater than spleen greater than lungs (the three highest tissues measured). Distribution is not dosage-dependant. It is extensively metabolized with less than 2% of recovered ^{14}C radioactivity representing the parent compound. Twenty-eight metabolites were identified in the urine, and 28 in the feces. Ten metabolites were identified in both urine and feces. Prometryn is excreted predominantly in the urine and feces, with slightly higher concentrations in the urine. The 7-day recovery of ^{14}C radioactivity averaged 95% for all dosing groups.

B. Toxicological Endpoints

1. *Acute toxicity*. The developmental NOEL of 12 mg/kg/day from a developmental study was recommend for the acute dietary risk assessment.

2. *Short - and intermediate - term toxicity.* The developmental NOEL of 12 mg/kg/day from a developmental study was recommend for the short- and intermediate- term dermal and inhalation risk assessments.

3. *Chronic toxicity*. EPA has established the RfD for prometryn at 0.04 mg/kg/day. This RfD is based on upon the chronic feeding study in dogs with a NOEL of 3.75 mg/kg/day with a 100-fold safety factor to account for interspecies extrapolation and intraspecies variability.

4. *Carcinogenicity*. The Health Effects Division Reference Dose (RfD) Committee classified prometryn as a

Group E chemical (no evidence of human carcinogenic potential).

C. Exposures and Risks

1. *From food and feed uses.* Tolerances have been established (40 CFR 180.222(a)) for the residues of prometryn, 2,4-bis(isopropylamino)-6-methylthio-s-triazine, in celery at 0.5 ppm; corn forage, fresh corn and corn grain at 0.25 ppm; cotton at 1 ppm: cottonseed at 0.25 ppm; and pigeon peas at 0.25 ppm.. Tolerances with regional registration have been established (40 CFR 180.222(b)) for the residues of prometryn in dill at 0.3 ppm and parsley at 0.1 ppm. Risk assessments were conducted by EPA to assess dietary exposures and risks from prometryn as follows:

i. *Acute exposure and risk.* Acute dietary risk assessments are performed for a pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a one day or single exposure. The Margin of Exposure (MOE) value for females (13 years and older) was 1,200,000. This value is significantly higher than the Agency's level of concern of 100 which is adequate to ensure protection for females 13 and older..

ii. *Chronic exposure and risk.* Assuming 100% of the crop are treated and residues are at tolerance levels the theoretical maximum residue contribution (TMRC) from the established and proposed tolerances is 0.000056 mg/kg/day and utilizes less than 1% of the RfD for the U.S. Population. For exposure of the most highly exposed subgroup in the population, non-nursing infants, the TMRC is 0.0016 mg/kg/day which utilizes less than 1% of the RfD.

2. *From drinking water.* Despite the potential for exposure through drinking water, EPA has concluded that the percentage of the RfD that will be utilized by dietary exposure (including drinking water exposure) to residues of prometryn does not exceed 100% for any of the population subgroups. Considering food only, the population subgroup with the largest percentage of the RfD occupied is 0.0000056 mg/kg/day at < 1% of the RfD. Therefore taking into account the completeness and reliability of the toxicity data and the conservative exposure assessment, EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to prometryn residues.

3. *From non-dietary exposure.* Prometryn is currently not registered for residential use such as turf and ornamentals. Therefore there is no expectation of non-occupational residential exposures.

4. *Cumulative exposure to substances with common mechanism of toxicity.* Prometryn is a member of the triazine class of pesticides. Other members of this class include atrazine, simazine, cyanazine, prometon, propazine, metribuzin, hexazinone, ametryn, terbutryne, dipropetryn, and ethiozin.

Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.'' The Agency believes that ''available information'' in this context might include not only toxicity, chemistry, and exposure data, but also scientific policies and methodologies for understanding common mechanisms of toxicity and conducting cumulative risk assessments. For most pesticides, although the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA does not at this time have the methodologies to resolve the complex scientific issues concerning common mechanism of toxicity in a meaningful way. EPA has begun a pilot process to study this issue further through the examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will increase the Agency's scientific understanding of this question such that EPA will be able to develop and apply scientific principles for better determining which chemicals have a common mechanism of toxicity and evaluating the cumulative effects of such chemicals. The Agency anticipates, however, that even as its understanding of the science of common mechanisms increases, decisions on specific classes of chemicals will be heavily dependent on chemical specific data, much of which may not be presently available.

Although at present the Agency does not know how to apply the information in its files concerning common mechanism issues to most risk assessments, there are pesticides as to which the common mechanism issues can be resolved. These pesticides include pesticides that are toxicologically dissimilar to existing chemical substances (in which case the Agency can conclude that it is unlikely that a pesticide shares a common mechanism of activity with other substances) and pesticides that produce a common toxic metabolite (in which case common mechanism of activity will be assumed).

EPA does not have, at this time, available data to determine whether prometryn has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. The Agency has determined that there are no metabolites of toxicological concern associated with prometryn. For the purposes of this tolerance action, therefore, EPA has not assumed that prometryn has a common mechanism of toxicity with other substances.

D. Aggregate Risks and Determination of Safety for Infants and Children

1. *Safety factor for infants and children*— i. *In general.* In assessing the potential for additional sensitivity of infants and children to residues of prometryn, EPA considered data from developmental toxicity studies in the rat and rabbit and a two-generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from pesticide exposure during prenatal development to one or both parents. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for pre-and post-natal toxicity and the completeness of the database unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard MOE and uncertainty factor (usually 100 for inter- and intra-species variability)) and not the additional tenfold MOE/uncertainty factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard MOE/safety factor.

ii. *Developmental and reproductive toxicity studies.* The pre- and post-natal toxicology data base for prometryn is complete with respect to current toxicological data requirements. The results of these studies indicate that infants and children are not more

sensitive to exposure, based on the results of the oral rat and rabbit developmental toxicity studies and the 2-generation reproductive toxicity study in rats. The developmental studies in rats and rabbits both have the maternal NOELs and LOELs, respectively, and demonstrate that no prenatal extra sensitivity is present. However, based on the developmental effects observed in rabbits, an acute dietary risk assessment was performed for women age 13 and older. The MOE was calculated as 1,200,000. Therefore, EPA concludes that reliable data support use of the standard 100-fold margin of exposure/uncertainty factor and that an additional tenfold safety factor is not needed to protect infants and children.

2. *Acute risk*. The acute aggregate dietary MOE was calculated to be 1,200,000 for females age 13 and older (accounts for both maternal and fetal exposure), the population subgroup of concern. The MOE calculations were based on the developmental NOEL in rabbits of 12 mg/kg. This risk assessment assumed 100% of the crop was treated with tolerance level residues on all treated crops consumed, resulting in a significant over estimate of dietary exposure. The large acute dietary MOE calculated for females age 13 and older provides assurance the there is a reasonable certainty of no harm for infants and children to prometryn.

3. *Chronic risk*. Using the conservative exposure assumptions described above, EPA has concluded that aggregate exposure to prometryn from food will utilize less than 1% of the RfD for infants and children. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. There are no chronic exposure scenarios of non-dietary uses of prometryn which would contribute to the aggregate risk. Taking into account the completeness and reliability of the toxicity data and the conservative exposure assessment, EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to prometryn residues.

III. Other Considerations

A. Metabolism In Plants and Animals

The metabolism of prometryn in plants and animals is adequately understood for purposes of this tolerance.

B. Analytical Enforcement Methodology

An adequate analytical method, gas chromatograph is available in PAM Vol. II, for plant to enforce the tolerance expression.

C. Magnitude of Residues

The nature of the residue in plants is adequately understood for the purposes of this tolerance. Secondary residues in animals commodities are not expected to exceed existing tolerances as result to this use in Canada.

D. International Residue Limits

There are no Codex or Mexican limits for prometryn on carrots. This proposal will harmonize tolerances with 0.1 pm Canadian maximum limit for residues in carrots.

E. Rotational Crop Restrictions

Since the use is on carrots grown in Canada, rotational crop issues are not relevant.

IV. Conclusion

There are presently no actions pending against the continued registration of this chemical. Based on the information and data considered, the Agency has determined that the tolerance established by amending 40 CFR 180.222 would protect the public health. Therefore, it is proposed that tolerances be established for residues of prometryn in carrots at 0.1 ppm.

V. Public Docket

EPA has established a record for this rulemaking under docket control number [OPP–300619] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

Electronic comments may be sent directly to EPA at:
opp-docket@epamail.epa.gov.

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any from of encryption.

The official record for this rulemaking, as well as the public version, as described above will be kept in paper from. Accordingly, EPA will transfer any copies of comments received electronically into printed, paper from as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the Virginia address in ''ADDRESSES'' at the beginning of this document.

VI. Regulatory Assessment Requirements

Under Executive Order 12866 (58 FR 51735, Oct. 4, 1993), the Agency must determine whether the regulatory action is ''significant'' and therefore subject to all the requirements of the Executive Order (i.e., Regulatory Impact Analysis, review by the Office of Management and Budget (OMB)). Under section 3(f), the order defines ''significant'' as those actions likely to lead to a rule (1) having an annual effect on the economy of $100 million or more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also known as ''economically significant''); (2) creating serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement, grants, user fees, or loan programs; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order. Pursuant to the terms of this Executive Order, EPA has determined that this proposed rule is not ''significant'' and is therefore not subject to OMB review. Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96–354, 94 Stat. 1164, 5 U.S.C. 601–612), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in the **Federal Register** of May 4, 1981 (46 FR 24950).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: February 17, 1998.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Therefore, it is proposed that 40 CFR Part 180 be amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 346a and 371.

2. In § 180.222 by amending paragraph (a) by alphabetically adding the following commodity to the table to read as follows:

§ 180.222 Prometryn; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * *	* *
Carrots[1]	0.1
* * * * *	* *

[1]There are no U.S. registrations as of February 25, 1998 for use on carrots.

* * * * *

[FR Doc. 98–4804 Filed 2–24–98; 8:45 am]

BILLING CODE 6560–50–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 50

RIN 0930–ZA00

Simplification of Grant Appeals Process

AGENCY: HHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: Pursuant to 42 CFR Part 50, Subpart D, the Indian Health Service (IHS) and the Substance Abuse and Mental Health Services Administration (SAMHSA) (formerly, the Alcohol, Drug Abuse and Mental Health Administration) have provided an informal level of appeal on those grant related disputes subject to the departmental appeal procedures codified at 45 CFR Part 16.[1] These agencies are proposing by this notice to amend 42 CFR Part 50, Subpart D, to remove IHS and ADAMHA (now SAMHSA) from the list of agencies to which these informal appeal procedures apply and thus permit aggrieved grantees direct access to the Departmental Grant Appeals Board and that board's original jurisdiction.

DATES: Written comment must be received on or before April 27, 1998.

ADDRESSES: Written comments on the proposed rule must be sent to Thomas M. Reynolds, Room 13C–20, Parklawn Bldg., 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: For the Indian Health Service, Ms. M. Kay Carpentier, (301) 443–5204; for the Substance Abuse and Mental Health Services Administration, Thomas M. Reynolds, (301) 443–0179.

SUPPLEMENTARY INFORMATION: When the Department first established its Departmental Grant Appeals Board (now the Departmental Appeals Board), there was no provision for the Department's subordinate agencies to first review the disputed actions of officials prior to appeal at the Departmental level. However, it quickly became apparent that a number of disputes could and would, be resolved quickly by informal means if the grantees' complaints were surfaced to management levels within the HHS subordinate agencies. As a result, the regulations at 45 CFR Part 16 were revised to permit subordinate agencies to interpose an ''informal'' level of appeal prior to submission of an appeal to the Departmental Appeals Board. Various agencies in the Public Health Service (which has since been reorganized) chose to institute an intermediate informal review process as is currently described in 42 CFR Part 50, Subpart D. The intermediate level of appeal provided these agencies with an opportunity to relatively quickly and economically reverse erroneous Federal decisions, or to reassure grantees that a decision adverse to them was indeed an ''agency'' decision. At the time these regulations were instituted, this informal process was of significant benefit to both grantees and the subordinate agencies. Based on the lessons learned from this process and other means, IHS and SAMHSA instituted a policy of reviewing carefully the adverse determinations of their employees prior to permitting them to be issued so as to avoid erroneous determinations which would be subject to reversal upon appeal at the informal level. These agencies believe that they have reached the point where the adverse determinations being issued in recent years generally represent their best judgment.

The Department therefore believes that, for these agencies and their grantees, this informal process is no longer of benefit, and the cost in time and expense to the grantee is no longer warranted. Consequently, the Department is proposing to amend 42 CFR part 50, Subpart D, to remove IHS and ADAMHA (now SAMHSA) from the list of Agencies to which the regulations apply. As a result, under this proposal, grantees wishing to appeal IHS's and SAMHSA's eligible adverse determinations would be entitled to appeal such determinations directly to the Departmental Appeals Board. In addition, 42 CFR Part 50, Subpart D, will be revised to reflect organizational changes in the Department, particularly that pertaining to the Public Health Service.

Economic Impact

This rule does not have cost implications for the economy of $100 million or otherwise meet the criteria for a major rule under Executive Order 12291, and therefore does not require a regulation impact analysis. Further, this regulation will not have a significant impact on a substantial number of small entities, and therefore does not require a regulatory flexibility analysis under the Regulatory Flexibility Act of 1980.

Regulatory Evaluation

This Proposal is not a significant regulatory action under Section 3(f) of the Executive Order 12866 and does not require an assessment of the potential costs and benefits under Section 6(a)(3) of that Order and so has been exempted from review by the Office of Management and Budget under that Order.

Paperwork Reduction Act

There are no new paperwork requirements subject to the Office of Management and Budget approval under the Paperwork Reduction Act of 1980.

List of Subjects in 42 CFR Part 50

Administrative practice and procedure, Grant programs—health, Health care.

Approved: February 18, 1998.

Donna E. Shalala,

Secretary.

For the reasons set forth in the preamble, the Department proposes to amend Subpart D of Part 50 of Title 42 of the Code of Federal Regulations as follows:

[1] Section 161 of the ADAMHA Reorganization Act, Pub. L. 102–321 (July 10, 1992), provides that references in any regulations to ADAMHA shall be deemed to refer to SAMHSA and, accordingly, the informal level of appeal is available to SAMHSA's grantees.